

ASSEMBLY BILL

No. 1397

Introduced by Assembly Member Hill
(Principal coauthor: Senator Leno)

February 27, 2009

An act to amend Section 1644.5 of the Health and Safety Code, relating to tissue donation.

LEGISLATIVE COUNSEL'S DIGEST

AB 1397, as introduced, Hill. Tissue donation.

Existing law prohibits the transfer of any tissues, as defined, into the body of another person by means of transplantation, unless the donor of the tissues has been screened and found nonreactive for evidence of infection with human immunodeficiency virus (HIV), agents of viral hepatitis (HBV and HCV), human T lymphotropic virus-1 (HTLV-1), and syphilis, except as provided.

Existing law requires that all donors of sperm be screened and found nonreactive under the above provisions, except as provided. Under existing law, a sperm donor who has tested reactive for HIV or HTLV-1 may be used for insemination or advanced reproductive technology for a recipient who has tested negative only after processing to minimize the infectiousness of the sperm. The State Department of Public Health is required to adopt regulations by January 1, 2010, regulating facilities that perform this processing.

This bill would, instead, make the adoption of the above regulations voluntary.

Existing law further requires the physician providing insemination or advanced reproductive technologies to, among other things, inform the recipient that the processing may not eliminate the risk of infection,

that the sperm may be tested to ensure that it is free from HIV or HTLV-1, and about the potential adverse effects of testing on the sperm.

This bill would remove the requirement that the recipient be informed of the availability and consequences of further testing.

Under existing law, the physician performing insemination or advanced reproductive technology is required to provide prophylactic treatments, follow-up testing, and monitoring, as specified, to the recipient to minimize the risk of infection.

This bill would remove those requirements.

Existing law allows the use of sperm from a donor who has tested reactive for HIV or HTLV-1 if the recipient has also previously been documented with HIV or HTLV-1 and where mutual consent has been obtained.

This bill would remove this provision. The bill would also make all of the provisions above applicable to donors who have tested reactive for any of the human T lymphotropic viruses.

Vote: majority. Appropriation: no. Fiscal committee: yes.
State-mandated local program: no.

The people of the State of California do enact as follows:

- 1 SECTION 1. Section 1644.5 of the Health and Safety Code is
- 2 amended to read:
- 3 1644.5. (a) No tissues shall be transferred into the body of
- 4 another person by means of transplantation, unless the donor of
- 5 the tissues has been screened and found nonreactive by laboratory
- 6 tests for evidence of infection with HIV, agents of viral hepatitis
- 7 (HBV and HCV), human T lymphotropic virus-1 (HTLV-1) virus
- 8 (HTLV), and syphilis, except as provided in subdivision (c). The
- 9 department may adopt regulations requiring additional screening
- 10 tests of donors of tissues when, in the opinion of the department,
- 11 the action is necessary for the protection of the public, donors, or
- 12 recipients.
- 13 (b) Notwithstanding subdivision (a), infectious disease screening
- 14 of blood and blood products shall be carried out solely in
- 15 accordance with Article 2 (commencing with Section 1601) of
- 16 Chapter 4.
- 17 (c) All donors of sperm shall be screened and found nonreactive
- 18 as required under subdivision (a), except in the following instances:

1 (1) A recipient of sperm, from a sperm donor known to the
2 recipient, may waive a second or other repeat testing of that donor
3 if the recipient is informed of the requirements for testing donors
4 under this section and signs a written waiver.

5 (2) A recipient of sperm may consent to therapeutic insemination
6 of sperm or use of sperm in other advanced reproductive
7 technologies even if the sperm donor is found reactive for hepatitis
8 B, hepatitis C, syphilis, HIV or ~~HTLV-1~~ *HTLV* if the sperm donor
9 is the spouse of, partner of, or designated donor for that recipient.
10 The physician providing insemination or advanced reproductive
11 technology services shall advise the donor and recipient of the
12 potential medical risks associated with receiving sperm from a
13 reactive donor. The donor and the recipient shall sign a document
14 affirming that each comprehends the medical repercussions of
15 using sperm from a reactive donor for the proposed procedure and
16 that each consents to it. Copies of the document shall be placed in
17 the medical records of the donor and the recipient.

18 (3) (A) Sperm whose donor has tested reactive for syphilis may
19 be used for the purposes of insemination or advanced reproductive
20 technology only after the donor has been treated for syphilis. Sperm
21 whose donor has tested reactive for hepatitis B may be used for
22 the purposes of insemination or advanced reproductive technology
23 only after the recipient has been vaccinated against hepatitis B.

24 (B) (i) Sperm whose donor has tested reactive for HIV or
25 ~~HTLV-1~~ *HTLV* may be used for the purposes of insemination or
26 advanced reproductive technology for a recipient testing negative
27 for HIV or ~~HTLV-1~~ *HTLV* only after the donor's sperm has been
28 effectively processed to minimize the infectiousness of the sperm
29 for that specific donation and where informed and mutual consent
30 has occurred.

31 (ii) The department ~~shall~~ *may* adopt regulations ~~by January 1,~~
32 ~~2010,~~ regulating facilities that perform sperm processing, pursuant
33 to this subparagraph, that prescribe standards for the handling and
34 storage of sperm samples of carriers of HIV, ~~HTLV-1~~ *HTLV*, or
35 any other virus as deemed appropriate by the department. ~~Until~~
36 ~~the department adopts these~~ *In the absence of* regulations, facilities
37 that perform sperm processing shall follow facility and sperm
38 processing guidelines developed by the American Society of
39 Reproductive Medicine.

(iii) Prior to insemination or other advanced reproductive technology services, the physician shall inform the recipient of sperm from a donor who has tested reactive for HIV or HTLV-1 that sperm processing may not eliminate all risks of HIV or HTLV-1 transmission, and that the sperm may be tested to determine whether or not it is free of HIV or HTLV-1. The physician shall also inform the recipient of potential adverse effects the testing may have on the processed sperm.

(iv) The physician providing insemination or advanced reproductive technology services shall provide, as appropriate, prophylactic treatments, including, but not limited to, antiretroviral treatments, to the recipient to reduce the risk of acquiring infection during, and subsequent to, insemination or advanced reproductive technology. The physician providing *insemination or* advanced reproductive technology services shall also verify, and document in the recipient's medical record, that the donor of sperm who tests reactive for HIV or HTLV-1 *HTLV* is under the care of a physician managing the HIV or HTLV-1 to minimize the risk of transmission during the course of insemination or advanced reproductive technology services. The physician shall perform appropriate followup testing of the recipient for HIV or HTLV-1 following the insemination or other advanced reproductive technology, and recommend ongoing monitoring by a physician during treatment and pregnancy. The physician shall also recommend in the sperm recipient's medical record that the recipient be monitored during treatment and pregnancy *HTLV*.

(v) In the event that the recipient tests reactive for *becomes* HIV or HTLV-1 following insemination or other advanced reproductive technology, the physician *HTLV positive during the course of the pregnancy, the physician assuming ongoing management of the pregnancy* shall inform the recipient of appropriate treatments during and after pregnancy, and of treatments or procedures that may reduce the risk of transmission to the offspring, *or provide information regarding referral to a physician who can provide that information.*

(vi) Sperm whose donor has tested reactive for HIV or HTLV-1 may be used for the purposes of insemination or advanced reproductive technology if the recipient already has been previously documented with HIV or HTLV-1 infection, and where informed and mutual consent has occurred.

1 (4) The penalties of Section 1621.5 shall not apply to a sperm
2 donor covered under this subdivision.

3 (d) Subdivision (a) shall not apply to the transplantation of tissue
4 from a donor who has not been tested or, with the exception of
5 HIV and ~~HTLV-1~~ *HTLV*, has been found reactive for the infectious
6 diseases listed in subdivision (a) or for which the department has,
7 by regulation, required additional screening tests, if both of the
8 following conditions are satisfied:

9 (1) The physician and surgeon performing the transplantation
10 has determined any one or more of the following:

11 (A) Without the transplantation the intended recipient will most
12 likely die during the period of time necessary to obtain other tissue
13 or to conduct the required tests.

14 (B) The intended recipient already is diagnosed with the
15 infectious disease for which the donor has tested positive.

16 (C) The symptoms from the infectious disease for which the
17 donor has tested positive will most likely not appear during the
18 intended recipient's likely lifespan after transplantation with the
19 tissue or may be treated prophylactically if they do appear.

20 (2) Consent for the use of the tissue has been obtained from the
21 recipient, if possible, or if not possible, from a member of the
22 recipient's family, or the recipient's legal guardian. For purposes
23 of this section, "family" shall mean spouse, adult son or daughter,
24 either parent, adult brother or sister, or grandparent.

25 (e) Human breast milk from donors who test reactive for agents
26 of viral hepatitis (HBV and HCV), ~~human T-lymphotrophic virus-1~~
27 ~~(HTLV-1)~~ *HTLV*, HIV, or syphilis shall not be used for deposit
28 into a milk bank for human ingestion in California.